

Current & Alternative Forms and Statistical Trends in Workplace Drug Testing

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2/21/2008



Federal Regulations

- Sept. 1986: Executive Order 12564
- Apr. 1988: "NIDA" Guidelines
- Dec. 1989: DOT Rules
- June 1994: Marijuana Cutoff Change
- Nov. 1998: Opiate Cutoff Change
- Aug. 2001: Proposed SVT Revisions/DOT Rule Changes
- Apr. 2004: Revised Mandatory Guidelines
- Apr. 2004: Proposed Mandatory Guidelines
 - ◆ Alternative Matrices
 - ◆ Alternative Technologies
- Nov. 2004: DOT Interim Final Rule

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URINE

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Urine Collection Procedure (1/2)

- Donor selects kit
- Donor provides specimen in privacy - Not Observed
- Collector measures temperature
- Collector pours specimen into bottle

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Urine Collection Procedure (2/2)

- Specimen bottle sealed & CCF completed
- Bottle & CCF placed in COC bag for transport to lab
- Specimen sent via Courier
- Collection Time: 10-15 minutes
- Considered Biohazardous

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Urine Specimen Validity Testing

- All Specimens:
 - ◆ pH
 - ◆ Creatinine
 - ◆ Specific Gravity when indicated
- TestSure™
 - ◆ Same as above
 - ◆ Oxidizing Adulterants (Chromates, Halogens, Nitrites)
 - ◆ Glutaraldehyde when indicated

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Urine Cutoffs

- Industry Standard Cutoffs
- HHS-5 (aka “NIDA”-5)

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Drugs Tested

<u>CLASS</u>	<u>CUTOFF</u>
“Amphetamines”	1000/500
♦ Amp, Methamphetamine	
Cocaine	300/150
♦ BE	
Marijuana Metabolite	50/15
“Opiates”	2000/2000
♦ Codeine, Morphine	
PCP	25/25

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Other Analytes

- MDMA best screened using a separate/specific test
- 6-MAM –
 - ♦ Heroin specific marker
 - ♦ Test if Morphine positive
- Prescription Drugs
 - ♦ “Expanded Opiates” (as part Opiate screen)
 - ♦ Hydrocodone, Hydromorphone
 - ♦ Requires lower cutoff (300/300)
 - ♦ Oxycodone (best detection with specific test)
 - ♦ Barbiturates, Benzodiazepines, Methadone, Methaqualone, Propoxyphene
- Alcohol

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Lab Receiving Process

- Pre-Sort
 - ♦ Specimen type
 - ♦ Regulated vs. non-regulated
- Accession
 - ♦ Verify specimen identification
 - ♦ Verify specimen integrity
 - ♦ Label
- Aliquot for screen

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Log-In



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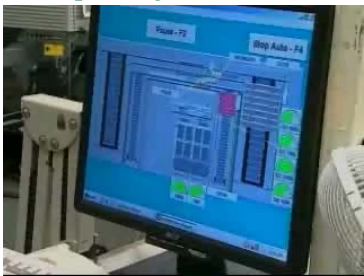
Aliquot




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Urine Aliquotting




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Lab Testing Processes

- Screen: enzyme immunoassay (EIA)
 - ◆ TAT: < 24 hrs

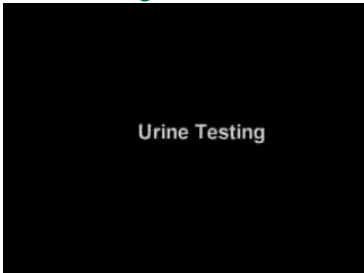


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Urine Screening




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Lab Testing Processes

- Screen: enzyme immunoassay (EIA)
 - ◆ TAT: < 24 hrs
- Re-aliquot if non-negative
- Extract
- Confirmation: GC(LC)/MS(/MS)
The "Gold Standard"
 - ◆ TAT: 48 - 72 hrs.




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GC/MS Extractions




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GC/MS




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Lab Certification Process

- Review chain of custody
 - ◆ External – CCF
 - ◆ Internal – Specimen & Aliquot
- Review analytical data
- If negative:
 - ◆ Complete CCF
 - ◆ Initial CCF
- If non-negative:
 - ◆ Same CS reviews screen and confirmation data
 - ◆ Complete CCF and compare CCF w/ Electronic report
 - ◆ Sign CCF
- Report results
 - ◆ Negative? → Electronic
 - ◆ Non-Negative? → CCF & Electronic


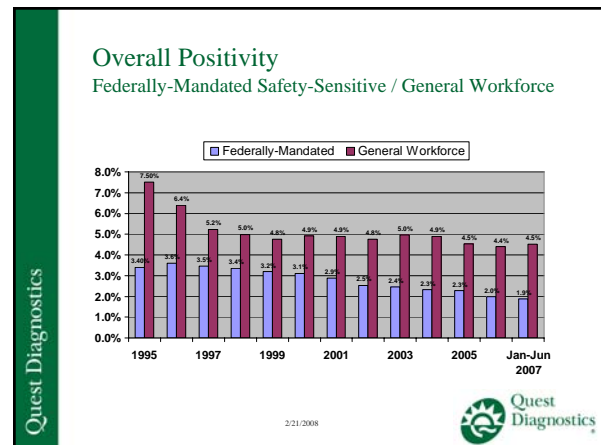
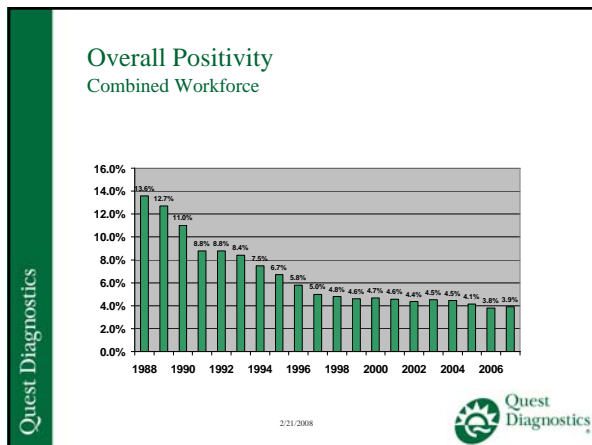
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Detection Window

- Detects use within past several days
- Detection times are dependent on Cutoff
- Cannot be used to determine if donor was “under the influence”


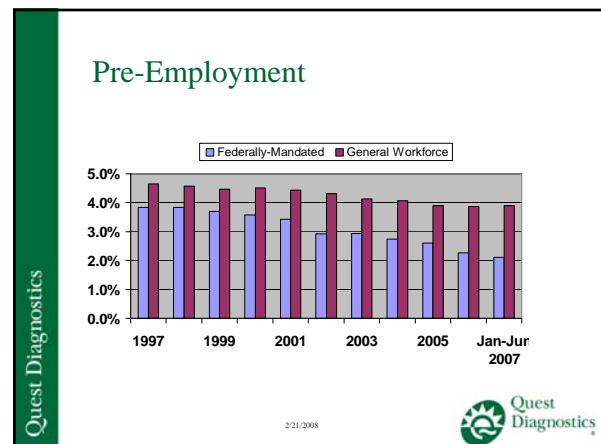
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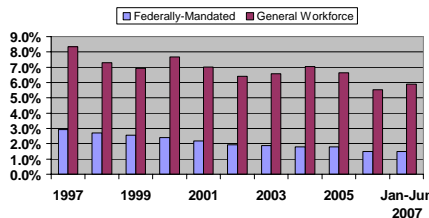
FMSS Detail

Type	2005	2006	2007
TDP	1.0%	0.9%	1.0%
DOT	2.1%	1.9%	1.8%
NRC	3.3%	3.2%	3.3%

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Random



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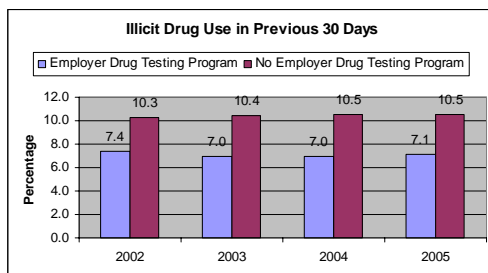
Percent of Specimens Tested by Testing Reason, 2001-2007

	FMSS (N=9.1 million)	GW (N=39 million)
Pre-Employment	46%	78%
Random	43%	10%
Other	11%	12%

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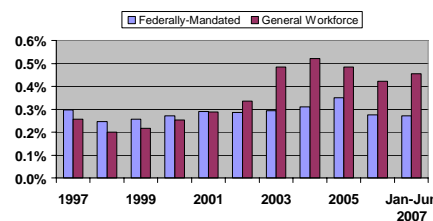
Effect of Workplace Drug Testing Programs Illicit Drug Use



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Amphetamines



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Amphetamine Class Positivity (GW – 1000/500)

	2002	2003	2004	2005	2006	Jan-Jun 2007
N (Millions)	5.6	5.6	5.8	5.8	6.8	3.3
Overall	0.33%	0.48%	0.52%	0.48%	0.42%	0.44%
Amp	0.28%	0.41%	0.44%	0.42%	0.37%	0.41%
Methamp	0.19%	0.32%	0.33%	0.26%	0.18%	0.16%
Both Amp & Methamp	0.14%	0.24%	0.25%	0.19%	0.00%	0.12%

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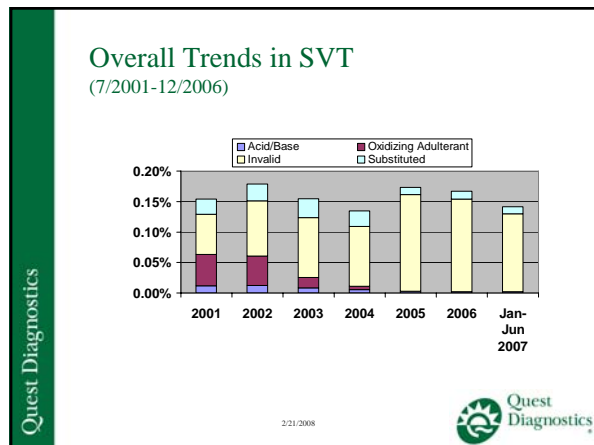
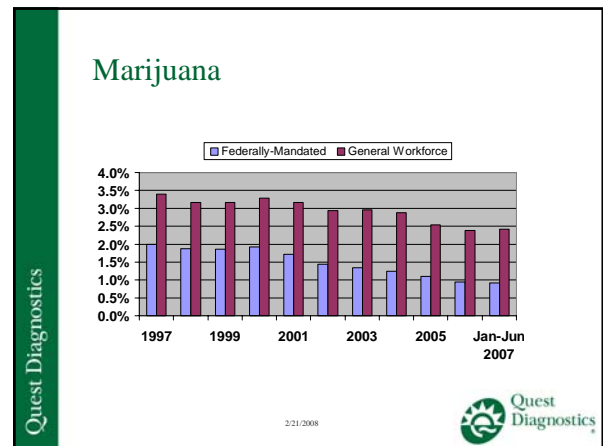
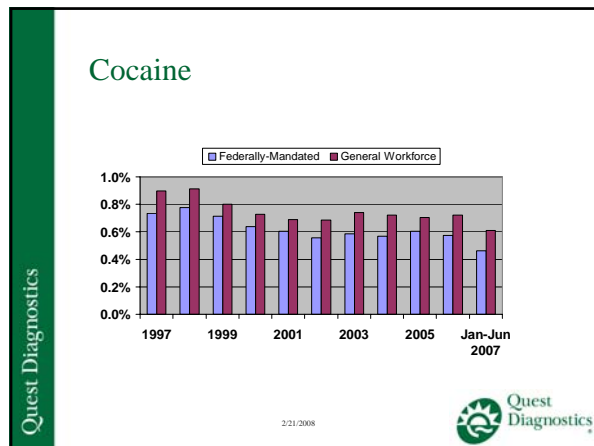


Amphetamine Class Positivity (FMSS – 1000/500)

	2002	2003	2004	2005	2006	Jan-Jun 2007
N (Millions)	1.2	1.2	1.2	1.3	2.1	0.9
Overall	0.29%	0.29%	0.31%	0.35%	0.28%	0.27%
Amp	0.21%	0.22%	0.24%	0.28%	0.22%	0.23%
Methamp	0.21%	0.22%	0.23%	0.25%	0.17%	0.15%
Both Amp & Methamp	0.14%	0.15%	0.16%	0.18%	0.00%	0.11%

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FMSS - Adulterated

Type	2005	2006	2007
TDP	0.00%	0.00%	0.02%
DOT	0.01%	0.00%	0.01%
NRC	0.01%	0.01%	0.01%

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FMSS - Substituted

Type	2005	2006	2007
TDP	0.18%	0.09%	0.12%
DOT	0.05%	0.05%	0.05%
NRC	0.03%	0.03%	0.02%

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FMSS - Dilute

Type	2005	2006	2007
TDP	2.36%	1.72%	1.77%
DOT	2.36%	2.26%	2.14%
NRC	0.76%	0.70%	0.63%

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FMSS - Invalid

Type	2005	2006	2007
TDP	0.17%	0.26%	0.27%
DOT	0.14%	0.12%	0.10%
NRC	0.08%	0.08%	0.11%

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Invalid Reasons: FMSS

	2004	2005	2006	2007
N (Thousands)	1.0	1.5	1.6	2.0
Bottle	8%	4%	4%	6%
Characteristics	0.6%	0.3%	0.8%	1.0%
Creatinine	17%	9%	15%	10%
GCMS	11%	6%	6%	4%
Immunoassay	19%	17%	14%	10%
Oxidant Activity	12%	26%	27%	27%
pH	32%	22%	20%	28%
Specific Gravity	6%	19%	17%	17%

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Invalid Reasons: FMSS Detail 2007

	TDP	DOT	NRC
N (Thousands)	0.2	1.7	0.1
Bottle	2%	7%	2%
Characteristics	0.0%	1.1%	0.0%
Creatinine	4%	11%	4%
GCMS	0%	5%	0%
Immunoassay	2%	11%	12%
Oxidant Activity	27%	27%	44%
pH	61%	24%	31%
Specific Gravity	4%	19%	6%

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Invalid Reasons: GW

	2004	2005	2006	2007
N (Thousands)	5.6	9.2	9.3	8.6
Bottle	1.6%	0.8%	1.5%	2.2%
Characteristics	0.9%	0.3%	0.7%	1.2%
Creatinine	12%	7%	12%	8%
GCMS	15%	6%	6%	7%
Immunoassay	22%	16%	16%	14%
Oxidant Activity	13%	23%	18%	19%
pH	33%	19%	20%	22%
Specific Gravity	8%	32%	30%	31%

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HAIR

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Hair Collection Procedure (1/3)

- Open sample collection kit and remove contents & fold foil into a 'V' shape
- Grasp a lock of hair from crown of the head and hold away from scalp
 - ◆ When laid flat across finger, there should be ~1 cm in width.
- Cut as close to scalp as possible
- Total collected: ~100 mg

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Hair Collection Procedure (2/3)

- Pinch foil closed and fold tightly around hair
- Place hair in specimen container (identification envelope)
- Seal envelope
- Complete CCF

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Hair Collection



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Hair Collection Procedure (3/3)

- Place envelope & CCF in COC bag for transport to lab
- Specimen sent by Overnight Courier Collection Time: 5-10 minutes
- Not considered Biohazardous

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Hair Collection Issues

- 90-day window requires ~4 cm hair length (closest to scalp)
- “Sparse” hair - May collect from 2-3 separate locations
- Bald/“Crew-Cut”: May collect from alternative body sites
 - ◆ Site must be noted on CCF

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Hair Specimen Validity Testing

- Observed Collection - Adulteration more difficult
- No lab tests for hair specimen validity

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Hair Cutoffs

- No Industry Standard Cutoffs

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Drugs Tested

<u>CLASS</u>	<u>CUTOFF</u>
"Amphetamines"	300/300
♦ Amp, Methamphetamine, MDMA	
"Cocaines"	300/300
♦ Cocaine, BE, CE	
Marijuana Metabolite	1.0/0.1
"Opiates"	500/500
♦ Codeine, Morphine, 6-MAM	
PCP	300/300

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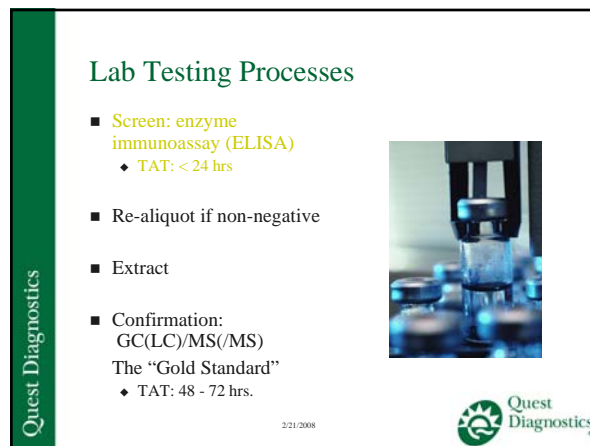
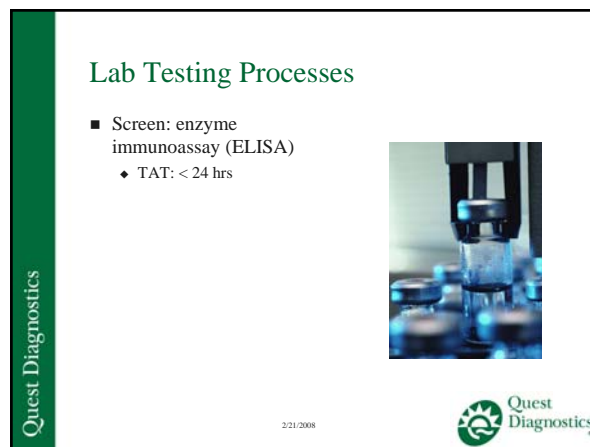
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Lab Receiving Process

- Pre-Sort
 - ♦ Specimen type
 - ♦ Regulated vs. non-regulated
- Accession
 - ♦ Verify specimen identification
 - ♦ Verify specimen integrity
 - ♦ Label
- Aliquot for screen
 - ♦ Extract

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Lab Certification Process

- Review chain of custody
 - ◆ External – CCF
 - ◆ Internal – Specimen & Aliquot
- Review analytical data
- Report results

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Detection Window

- Longer Detection Window than Urine - up to 90-days
- Detection times are dependent on Cutoff
- Will not reliably detect:
 - ◆ Single use
 - ◆ Use in first week of abuse


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ORAL - FLUID

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Oral-Fluid Collection Device



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Oral Fluid Collection Procedure (1/3)

- Nothing by mouth for 10 minutes
- Donor places collection pad between lower cheek and gums - gently rub until moist
- Pad remains in mouth for 3 minutes - Collects ~0.4 mL
- Donor places pad in specimen vial which contains buffer

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Oral Fluid Collection Procedure (2/3)

- Donor snaps off applicator wand
- Donor places cap on specimen vial
- Vial sealed
- CCF completed

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Oral-Fluid Collection



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Oral Fluid Collection Procedure (3/3)

- Vial & CCF placed in COC bag for transport to lab
- Specimen sent by Overnight Courier
- Collection Time: 5-10 minutes
- Not considered Biohazardous

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Specimen Validity Testing

- Observed Collection - Adulteration more difficult
- IgG measured as indicator of Specimen Validity - Common practice in Insurance Industry to validate that *Human* saliva collected

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Cutoffs

- No Industry Standard Cutoffs
- Collection device has ~X3 Dilution - Cutoffs are *not* directly comparable between different oral-fluid collection/testing devices!

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Drugs Tested

<u>CLASS</u>	<u>CUTOFF</u>
Amphetamine	100/40
Methamphetamine	40/40
♦ Methamphetamine, MDMA, MDA	
Cocaine Metab.	5/2
Marijuana (Parent)	1.0/0.5
"Opiates"	10/10
♦ Cod, Mor, HyCod, HyMor, 6-MAM	
PCP	1.0/0.5

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Lab Receiving Process

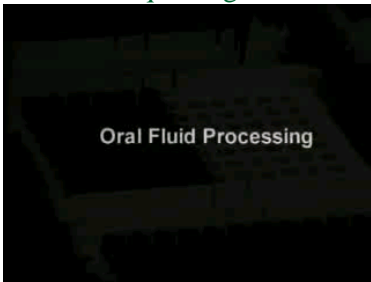
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 - ♦ Regulated vs. non-regulated
- Accession
 - ♦ Verify specimen identification
 - ♦ Verify specimen integrity
 - ♦ Label
- Aliquot for screen

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Oral-Fluid Aliquotting



Oral Fluid Processing


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Lab Testing Processes

- Screen: enzyme immunoassay (ELISA)
 - ◆ TAT: < 24 hrs
- Re-aliquot if non-negative
- Extract
- Confirmation: GC(LC)/MS(/MS)
The "Gold Standard"
 - ◆ TAT: 48 - 72 hrs.



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Lab Certification Process

- Review chain of custody
 - ◆ External – CCF
 - ◆ Internal – Specimen & Aliquot
- Review analytical data
- Report results

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Detection Window

- Shorter Detection Window than Urine
- Detection times are dependent on Cutoff
- Concentration in Oral Fluid is generally related to blood concentration - Indicator of **Recent** Use


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Point of Collection Test (POCT)

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Point of Collection Testing

- What is it?
 - ◆ An initial test conducted at the collection site. It can be a non-instrumented (visual read) or instrumented device.
- Available for Oral Fluid and Urine specimens


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POCT Process

- Specimen Type: Urine, Oral-Fluid
- Cutoff → Same as lab
- COC → Similar to lab
- QA/QC
 - ◆ Minimum each shipment/lot
- Equipment/Maintenance → Usually N/A
- Confirmation
 - ◆ “Full” Panel (Preferred)
 - ◆ Non-Negative analyte


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Instant Testing Urine

- Multiple varieties of testing kits
 - ◆ “Dip and Read”
 - ◆ “Integrated Cup”
- Fast turn-around time
- Entire collection process occurs on-site, anytime
- 1-9 drug test configurations
- May include SVT
- May require “activation” to start test
- Read results up to 60 minutes


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Urine POCT Result Interpretation

- Qualitative test – line (red) intensities and background color will vary and are not indicative of drug concentration
 - ◆ Line → Negative
 - ◆ No-Line → Non-Negative
- SVT Results read within 2-3 minutes of adding sample
- Drug Results usually read 5 minutes after adding sample
- Drug negative interpretation may be made once all lines (including control) are visible
- Non-Negative results may change (line may appear) if read later than 15-60 minutes (device dependent)
- Presumptive positive specimens sent to lab for confirmation


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Urine POCT Interpretation




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Instant Testing Oral-Fluid

- Multiple varieties of testing kits
- Fast turn-around time
- Entire collection process occurs on-site, anytime
- 2-7 drug test configurations (most “5-panel”)
- Doesn’t include SVT
- May require 2nd specimen for confirmation


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Oral-Fluid POCT Result Interpretation

- Qualitative test – line (red) intensities and background color will vary and are not indicative of drug concentration
 - ◆ Line → Negative
 - ◆ No-Line → Non-Negative
- Results must be read within 10-15 minutes of adding sample
- Drug negative interpretation may be made once all lines (including control) are visible
- Non-Negative results may change (line may appear) if read later than 15 minutes

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Presumptive Positive Specimens

- May require second oral-fluid collection
- Some employers collect urine
- Sent to lab for confirmation

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Cutoffs

- No Industry Standard Cutoffs
- No dilution with buffer - Neat Oral Fluid
- Some loss of THC on collector

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Drugs Tested

<u>CLASS</u>	<u>CUTOFF</u>
Amphetamine	50
Cocaine Metabolite	20
Marijuana (Parent)	50-100+
Methamphetamine	50
Opiates	40
PCP	10

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Detection Window

- Shorter Detection Window than Urine
- Detection times are dependent on Cutoff
- Concentration in Oral Fluid is generally related to blood concentration - Indicator of **Recent** Use

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Instant Testing Alcohol




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QED

- Compact collection/testing device
- Quantitative result readout
- Lateral flow test device
- Built in control spot
- D.O.T. approved
- Training program STT (screening test technician, CD ROM/Video)




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Breath Tube

- Compact collection/testing device
- Two Types
 - ◆ DOT – Qualitative
 - ◆ Requires electronic reader
 - ◆ Non-DOT – Semi-Quantitative
- D.O.T. approved
- Training program STT (screening test technician, CD ROM/Video)



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Comparison of Specimen Types

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Matrix Comparison – Detection Time

Matrix	Detection window	Advantages
Urine	1-3 days	Good detection times, easy to collect, current workplace standard but adulteration potential
Hair	45-90 days	Difficult to adulterate, good detection time but more expensive and hair length may be an issue
Oral Fluid	24-36 hours	Easy to collect and difficult to adulterate but shorter detection time

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Oral-Fluid vs. Urine

(January 2005 – December 2006)

	Oral-Fluid	Urine GW
N (Millions)	~2	~14
Positive	4.0%	4.4%
BY DRUG		
Amphetamines	0.16%	0.46%
Methamphetamine	0.33%	N/A
Cocaine	1.04%	0.73%
Marijuana	2.12%	2.45%
Opiates	0.40%	0.32%
PCP	0.02%	0.02%

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Oral-Fluid Amphetamines Positivity

	2003	2004	2005	2006
N (Thousands)	36	154	298	573
Overall Methamphetamine	0.46%	0.47%	0.46%	0.30%
Methamphetamine	0.44%	0.46%	0.45%	0.29%
MDMA	0.01%	0.01%	0.01%	0.02%
MDA	0.00%	0.00%	0.00%	0.00%
Amphetamine	0.13%	0.16%	0.18%	0.16%
Amp & Methamp	0.09%	0.10%	0.10%	0.06%

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Oral-Fluid Opiate Class Positivity

	2003	2004	2005	2006
N (Thousands)	36	154	298	573
Overall	0.66%	0.62%	0.71%	0.72%
Codeine	0.13%	0.08%	0.09%	0.08%
Morphine	0.04%	0.05%	0.03%	0.04%
Hydrocodone	0.51%	0.50%	0.60%	0.60%
6-MAM	0.02%	0.02%	0.01%	0.02%
Codeine & Morphine	0.01%	0.01%	0.00%	0.01%
Morphine & 6-MAM	0.02%	0.02%	0.01%	0.01%

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Current Trends – Urine Drug Testing

- Overall positivity rate stable to slight decrease
 - ◆ FMSS steady small decreases since 1999
 - ◆ GW stable since 2004
- Amphetamines
 - ◆ GW decreased in 2005 and 2006, slight increase early 2007
 - ◆ FMSS small increase in 2005 and decrease in 2006 & 2007
 - ◆ Methamphetamine down, while amphetamine up or stable
- Cocaine positivity
 - ◆ Down sharply in first half of 2007
- Marijuana
 - ◆ Decrease slowed
- SVT
 - ◆ Invalids – Stable
 - ◆ Dilute - Small steady decreases

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Questions ?

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